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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,391	08/21/2003	Martin Gleave	UBC.P-035	9734

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EXAMINER
BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,391	GLEAVE ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 7/8/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 4/8/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 7/8/05, claims 1-13 are pending in the application. Claims 11-13 have been withdrawn from consideration.

Response to Arguments--Claim Objections

Claims 3, 6 and 9 stand objected to for the reasons of record in the office action mailed 4/8/05.

Applicant's arguments are noted and considered responsive. The objections are maintained in so far as the generic claims are found non-allowable. Although there are claims that link inventions, the claims were restricted because the sequences are not considered proper Markush members. Therefore, the subject matter of claims 3, 6 and 9 that is not drawn to instant SEQ ID NO: 4 and the translation initiation site, is considered withdrawn as being drawn to non-elected subject matter and the claims are objected to because they contain subject matter that is withdrawn.

Response to Arguments--Claim Rejections - 35 USC § 112

Claims 1-5 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record in the office action mailed 4/8/05.

Applicant argues that the Branch et al. reference was relied upon for a teaching that not all complementary oligonucleotides are effective as antisense. Applicant argues that applicant discloses a specific human antisense species that have been shown to have antisense activity in human melanoma cells. Actually, the Branch et al. reference was relied upon for the unpredictability of predicting RNA accessibility in vivo (see page 6 of the office action mailed 4/8/05), while the specification discloses *in vitro* testing. It is noted that applicant has supplied a declaration under 37 CFR 1.132 filed 7/8/05 that enables the claims specifically drawn to antisense oligonucleotide SEQ ID NO: 4, but the instant invention encompasses claims that are drawn to any therapeutic agent or antisense oligonucleotide targeted to clusterin. The 35 U.S.C. 112, first paragraph, rejection as set forth in the office action mailed on 4/8/05 was primarily based on the unpredictability of *in vivo* delivery of the therapeutic agent and applicant has not supplied data that would overcome this unpredictability for any therapeutic agent or antisense oligonucleotide targeted to clusterin *in vivo*. Applicant argues that the references cited by the examiner are old in this rapidly developing technology. This is not persuasive because the issue of delivery remains to be the main obstacle for antisense oligonucleotide delivery and applicant has not supplied data to suggest otherwise for the scope of the instant

invention. As further evidenced by Aoki et al. (Clinical and Experimental Pharmacology and Physiology (2003) 30, 96-102), "the delivery and approach of antisense molecules to intracellular target RNA seems to be a crucial limiting factor in exerting the potential antisense effects" (see introduction).

The declaration under 37 CFR 1.132 filed 7/8/05 has been considered. The declaration under 37 CFR 1.132 is sufficient to overcome the 35 U.S.C. 112, first paragraph rejection of claims specifically drawn to a method of treatment in a mammalian subject comprising the step of administering an antisense oligonucleotide consisting of SEQ ID NO: 4, but is not enabling for the scope of administering any therapeutic agent or antisense oligonucleotide for the treatment of melanoma in a mammalian subject.

Response to Arguments--Claim Rejections - 35 USC § 102

Claims 1-5 stand rejected under 35 U.S.C. 102(e) as being anticipated by Monia et al. (US 2004/0053874), for the reasons of record set forth in the office action mailed 4/8/05. It is noted that the examiner inadvertently typed 102(a) rather than 102(e) in the rejection of record.

Applicant argues that since Monia et al. do not teach that targeting clusterin expression would be appropriate for the treatment of melanoma, Monia et al. do not anticipate the instant invention.

Applicant's argument has been considered but is not found persuasive. Contrary to applicant's assertions, Monia et al. teach a method of treating an animal having a disease or condition associated with clusterin comprising

administering to said animal a therapeutically effective amount of an antisense compound targeted to a nucleic acid molecule encoding clusterin, wherein said compound inhibits the expression of clusterin. Contrary to applicant's assertion regarding there needing to be a teaching of the method having the specific outcome of treating melanoma, Monia et al. teach the method step instantly claimed and would therefore be considered to necessarily treat melanoma as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Therefore, the rejection is considered proper and maintained.

Claims 1-5, 9 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gleave et al. (WO 00/49937), for the reasons of record set forth in the office action mailed 4/8/05.

Applicant argues that since Gleave et al. do not teach that targeting clusterin expression would be appropriate for the treatment of melanoma, Gleave et al. do not anticipate the instant invention.

Applicant's argument has been considered but is not found persuasive. Contrary to applicant's assertions, Gleave et al. teach a method of treating cancer in a mammalian subject comprising the administration of an antisense oligonucleotide effective to inhibit expression of TRPM-2 (another name for clusterin) in tumor cells. Contrary to applicant's assertion regarding there needing to be a teaching of the method having the specific outcome of treating melanoma, Gleave et al. teach the method step instantly claimed and would therefore be considered to necessarily treat melanoma as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Therefore, the rejection is considered proper and maintained.

Claims 1-5, 9 and 10 stand rejected under 35 U.S.C. 102(a) as being anticipated by Gleave (US 2002/0128220), for the reasons of record set forth in the office action mailed 4/8/05.

Applicant argues that since Gleave does not teach that targeting clusterin expression would be appropriate for the treatment of melanoma, Gleave does not anticipate the instant invention.

Applicant's argument has been considered but is not found persuasive. Contrary to applicant's assertions, Gleave teaches a method of treating cancer in a mammalian subject comprising the administration of an antisense oligonucleotide effective to inhibit expression of TRPM-2 (another name for clusterin) in tumor cells. Contrary to applicant's assertion regarding there needing to be a teaching of the method having the specific outcome of treating melanoma, Gleave teaches the method step instantly claimed and would therefore be considered to necessarily treat melanoma as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Therefore, the rejection is considered proper and maintained.

Response to Arguments--Claim Rejections - 35 USC § 103(a)

Claims 1-10 stand rejected under 35 U.S.C. 103(a), as being unpatentable over Gleave et al. (WO 00/49937), in view of Baracchini et al. (US 5,801,154), for the reasons of record set forth in the office action mailed 4/8/05.

Applicant argues that Baracchini et al. is cited only with respect to backbone modifications and does not overcome the fact that Gleave et al. does not teach the treatment of melanoma. Applicant asserts that the combination of these references do not suggest the claimed invention which is a method of treating melanoma.

Applicant's argument has been considered but is not found persuasive. Contrary to applicant's assertions, Gleave et al. teach a method of treating cancer in a mammalian subject comprising the administration of an antisense oligonucleotide effective to inhibit expression of TRPM-2 (another name for clusterin) in tumor cells. Contrary to applicant's assertion regarding there needing to be a teaching of the method having the specific outcome of treating melanoma, Gleave et al. teach the method step instantly claimed and would therefore be considered to necessarily treat melanoma as instantly claimed. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making,

the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Therefore, the rejection is considered proper and maintained.

Therefore, the 35 U.S.C. 103(a) rejection set forth in the official office action mailed on 4/8/05 is considered proper and maintained.

Response to Arguments—Double Patenting Rejection

Claims 1, 2, 9 and 10 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending application no. 10/828,394, which has a common inventor, for the reasons of record set forth in the office action mailed 4/8/05. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain methods with overlapping scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues that application '394 claims treatment of cancerous angiogenesis related diseases using materials that inhibit clusterin expression. Applicant argues that the present claims are directed to treatment of melanoma using the same type of materials. Applicant asserts that the examiner has not established that melanoma is a cancerous angiogenesis related disease, and that melanoma is not mentioned in application '394.

Applicant's arguments are based on the intended use of each of the methods. The claims of application '394 are drawn to the same method steps that are instantly claimed and would therefore be considered to necessarily have the instantly claimed outcome. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Therefore, the rejection is considered proper and maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
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